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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,039	07/12/2001	Shoulian Dong	3218.2A	3123

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,039

Applicant(s)

DONG ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/12/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 38-173 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 38, drawn to a method of analyzing a plurality of nucleic acid samples, classified in class 435, subclass 6.
- II. Claims 39-59, 64-84, 89-107, 112-133, and 138-159, drawn to a method of analyzing a first nucleic acid sample, classified in class 435, subclass 6.
- III. Claims 60-63, 85-88, 108-111, 134-137, and 160-173, drawn to a method of screening DNA sequence variation, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions I-III, employ different combination of sub-steps to achieve different outcomes. For example, Invention I is drawn to a method of analyzing a plurality of nucleic acid samples, while Invention II is drawn a method of analyzing a first nucleic acid sample wherein all of the involved sub-steps are different. The method of Invention III is also different in that it achieves a materially different outcome, detection of sequence variation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Additional Species Requirement for Group II

This application contains claims directed to the following patentably distinct species of the claimed invention: Group II involves the below patentably distinct species of preparing the second nucleic acid for detection:

- i) Method involving ligation of an adapter nucleic acid sequence (claims 39-58)
 - ia) SNP detection via probe-bead complex (claims 57 and 58)
 - ib) SNP detection via use of a mismatch binding protein (claim 59)
- ii) Method involving denaturation and renaturation of nucleic acids (claims 64-84)
 - iiia) SNP detection via probe-bead complex (claims 82 and 83)
 - iiib) SNP detection via use of a mismatch binding protein (claim 84)
- iii) Method involving arbitrarily primed PCR (claims 89-107)
 - iiia) SNP detection via probe-bead complex (claims 105 and 106)
 - iiib) SNP detection via use of a mismatch binding protein (claim 107)
- iv) Method involving probes on a solid support (claims 112-133)
 - iva) SNP detection via probe-bead complex (claims 131 and 132)
 - ivb) SNP detection via use of a mismatch binding protein (claim 133)
- v) Method involving fragmentation and binding of mismatch binding proteins (claims 138-159)
 - va) SNP detection via probe-bead complex (claims 157 and 158)
 - vb) SNP detection via use of a mismatch binding protein (claim 159)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and sub-species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Additional Species Requirement for Group III

This application contains claims directed to the following patentably distinct species of the claimed invention: Group III involves the below patentably distinct species of preparing the second nucleic acid for detection:

- i) Method involving ligation of an adapter nucleic acid sequence (claims 60-63 and 164-165)
- ii) Method involving denaturation and renaturation of nucleic acids (claims 85-88 and 166-167)
- iii) Method involving arbitrarily primed PCR (claims 108-111 and 168-169)
- iv) Method involving probes on a solid support (claims 134-137 and 170-171)
- v) Method involving fragmentation and binding of mismatch binding proteins (claims 160-163 and 172-173)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If


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applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

9/19/02




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/23/02